AMENDMENTS TO THE CLAIMS

Please amend claims 1, 6-9, 12-13, 17-19 and 21-22 as indicated below.

A complete list of claims as currently amended follows:

1. (currently amended) A controlled release central nervous system stimulant tablet formulation comprising:

(a) a core tablet comprising a mixture of:

(i) ~~a central nervous system stimulant~~ methylphenidate or a pharmaceutically acceptable salt or isomer thereof;

(ii) 1 to about 50% of the total weight of the core of a hydrogel polymer ~~a binder~~;

(iii) a diluent; and

(b) ~~a controlled release coating~~ an enteric coating surrounding the core tablet comprising;

(i) 45-80 weight percent based upon the total weight of the ~~controlled release~~ enteric coating of at least one enteric polymer; and

(ii) at least one conventional processing aid ~~a plasticizer; and~~

~~(iii) optionally a an anti-sticking agent; and~~

(c) an immediate release drug layer comprising;

(i) ~~a central nervous system stimulant~~ methylphenidate or a pharmaceutically acceptable salt or isomer thereof ;

(ii) a binder; and

(iii) optionally a stabilizer; and

(d) optionally an overcoat comprising;

(a) a coating agent wherein the tablet formulation exhibits the following dissolution profile when tested in a United States Pharmacopeia type 2 (paddle) apparatus at 50 pms in 900 ml of phosphate buffer with a pH of 7.5 and at 37°C: 1-35% of the methylphenidate is released after 1 hour; 5-40% of the methylphenidate is released after 2 hours; and not less than 70% is release after 10 hours ~~the central nervous system stimulant in the core and the immediate release drug layer is methylphenidate~~

~~or a pharmaceutically acceptable salt or isomer thereof~~.

2. (canceled).

3. (original) A controlled release formulation as defined in claim 1 where the diluent is selected from the group consisting of sugars, starches or vegetable oils, lactose monohydrate, calcium phosphate, dextrin, dextrose, maltitol, maltose, starch, sucrose or talc.

4. (original) A controlled release formulation as defined in claim 1 wherein said diluent comprises lactose monohydrate.

5. (canceled).

6. (currently amended) A controlled release formulation as defined in claim 1 where the ~~binder~~ hydrogel polymer in the core is selected from the group consisting of methyl cellulose, hydroxymethyl cellulose, polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene oxides, gums, acrylate polymers and methacrylate polymers.

7. (currently amended) A controlled release formulation as defined in claim 1 wherein the ~~binder~~ hydrogel polymer in the core is hydroxypropyl methylcellulose.

8. (currently amended) A controlled release formulation as defined in claim 1 where the ~~anti-sticking agent is not optional and~~ at least one conventional processing aid is selected from the group consisting of talc, glyceryl monostearates, calcium stearate, magnesium stearate, stearic acid, glyceryl behenate, and polyethylene glycol.

9. (currently amended) A controlled release formulation as defined in claim 1 wherein said ~~anti-sticking agent comprises~~ at least one conventional processing aid is

colloidal silicon dioxide and magnesium stearate.

10. (original) A controlled release formulation as defined in claim 1 wherein the enteric polymer is selected from a group consisting of zein, methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate trimellitate, shellac, polyvinyl acetate phthalate or mixtures thereof.

11. (original) A controlled release formulation as defined in claim 1 wherein the enteric coating polymer comprises a mixture of methacrylic acid copolymer and zein.

12. (currently amended) A controlled release formulation as defined in claim 1 wherein the ~~plasticizer~~ at least one conventional processing aid is selected from a group consisting of acetyltributyl citrate, triacetin, acetylated monoglyceride, coconut oil, poloxamer, acetyltriethyl citrate, glycerin sorbitol, diethyloxalate, diethylmalate, diethylfumerate, dibutylsuccinate, diethylmalonate, dioctylphthalate, dibutylphthalate, dibutylsebacate, triethyl citrate, tributylcitrate, glyceroltributyrate, polyethylene glycol, propylene glycol and mixtures thereof.

13. (currently amended) A controlled release formulation as defined in claim 1 wherein the ~~plasticizer~~ at least one conventional processing aid is acetyltributyl citrate.

14. (canceled).

15. (canceled)

16. (original) A controlled release formulation as defined in claim 1 wherein the binder employed in the immediate release drug layer is hydroxypropyl methylcellulose.

17. (currently amended) A controlled release formulation as defined in claim 1 wherein

the immediate release drug layer comprising said methylphenidate or a pharmaceutically acceptable salt or isomer thereof ~~central nervous system stimulant~~ reaches a peak blood plasma level in less than 3 hours and said ~~stimulant~~ blood plasma level declines in less than 5 hours.

18. (currently amended) The controlled release ~~methylphenidate~~ formulation of claim 17 wherein a second dose of ~~stimulant~~ methylphenidate or a pharmaceutically acceptable salt or isomer thereof reaches a peak blood plasma level of about 7.2 ng/ml in about 7 to 9 hours and said ~~stimulant~~ methylphenidate or a pharmaceutically acceptable salt or isomer thereof blood plasma level declines to about 1.4 ng/ml in about 14 to 18 hours.

19. (currently amended) A controlled release pharmaceutical tablet dosage formulation for oral administration comprising a tablet core ~~with~~ of methylphenidate or a pharmaceutically acceptable salt or isomer thereof mixed with a hydrogel polymer ~~a central nervous system stimulant~~, an enteric coating surrounding the tablet core and an immediate release dose comprising methylphenidate or a pharmaceutically acceptable salt or isomer thereof ~~a central nervous system stimulant~~ and a stabilizer, wherein the formulation when administered to humans exhibits (a) a maximum plasma concentration up to about 20 ng/ml; (b) an AUC_{0-24} up to about 200 ng/ml; (c) a T_{max2} of about 3 to about 12 hours and wherein ~~the central nervous system stimulant in the core and the immediate release layer is methylphenidate or a pharmaceutically acceptable salt or isomer thereof~~ the tablet formulation exhibits the following dissolution profile when tested in a United States Pharmacopeia type 2 (paddle) apparatus at 50 pms in 900 ml of phosphate buffer with a pH of 7.5 and at 37°C: 1-35% of the methylphenidate is released after 1 hour; 5-40% of the methylphenidate is released after 2 hours; and not less than 70% is release after 10 hours.

20.(original) The controlled release pharmaceutical dosage formulation as defined in Claim 19 wherein the formulation when administered to humans exhibits (a) a

maximum plasma concentration of about 3 to about 20 ng/ml; (b) an AUC_{0-24} of about 30 to about 200 (ng hr)/ml; and (c) a T_{max2} of about 3 to about 12 hours.

21. (currently amended) A controlled release tablet formulation consisting essentially of:

(a) a core tablet consisting essentially of a mixture of:

(i) 5-40 weight percent of methylphenidate or a pharmaceutically acceptable salt or isomer thereof ~~a central nervous stimulant~~;

(ii) 3-40 weight percent of a hydrogel polymer ~~binder~~; and

(iii) 25-90 weight percent of a diluent; and

(iv) 0.1-10 weight percent anti-sticking agent; and

(b) ~~a controlled release coating~~ an enteric coating surrounding the core tablet consisting essentially of;

(i) ~~10-85~~ 45-80 weight percent based upon the total weight of the ~~controlled release~~ enteric coating of an enteric polymer;

(ii) 0.5-15 weight percent based upon the total weight of the ~~controlled release~~ enteric coating of a plasticizer; and

(iii) an anti-sticking agent; and

(c) an immediate release drug layer consisting essentially of;

(a) 30-60 weight percent based upon the total weight of the immediate release ~~coating~~ layer of methylphenidate or a pharmaceutically acceptable salt or isomer thereof ~~a central nervous system stimulant~~; and

(b) 40-70 weight percent based upon the total weight of the immediate release layer of a binder; and

(c) 0.005- 5 weight percent based upon the total weight of the immediate release layer of a stabilizer wherein ~~the central nervous system stimulant in the core and the immediate release drug layer is methylphenidate or a pharmaceutically acceptable salt or isomer thereof~~ the tablet formulation exhibits the following dissolution profile when tested in a United States Pharmacopeia type 2 (paddle) apparatus at 50 pms in 900 ml of phosphate buffer with a pH of 7.5 and at 37°C: 1-35% of the methylphenidate is released after 1

hour; 5-40% of the methylphenidate is released after 2 hours; and not less than 70% is release after 10 hours

22. (currently amended) A controlled release tablet formulation as defined in claim 21 wherein:

(a) the core tablet consisting essentially of:

(i) 10-25 weight percent of methylphenidate or a pharmaceutically acceptable salt or isomer thereof ~~a central nervous stimulant~~;

(ii) 3-40 weight percent of a hydrogel polymer ~~binder~~; and

(iii) 45-85 weight percent of a diluent; and

(iv) 0.5-5 weight percent anti-sticking agent; and

(b) ~~a controlled release coating~~ an enteric coating surrounding the core tablet consisting essentially of;

(i) 45-80 weight percent based upon the total weight of the ~~controlled release~~ enteric coating of an enteric polymer;

(ii) 1- 5 weight percent based upon the total weight of the ~~controlled release~~ enteric coating of a plasticizer; and

(iii) an anti-sticking agent; and

(c) an immediate release drug layer consisting essentially of;

(a) 40-50 weight percent based upon the total weight of the immediate release ~~coating~~ layer of methylphenidate or a pharmaceutically acceptable salt or isomer thereof ~~a central nervous system stimulant; and~~

(b) 45-60 weight percent based upon the total weight of the immediate release layer of a binder; and

(c) 0.01-2 weight percent based upon the total weight of the immediate release layer of a stabilizer.

23. (canceled).

24. (original) A controlled release formulation as defined in claim 22 wherein the

enteric polymers comprises a mixture of methacrylic acid copolymer and zein.

25. (previously presented) A controlled release pharmaceutical dosage formulation as defined in claim 22 wherein the formulation when administered to humans exhibits (a) a maximum plasma concentration up to about 20 ng/ml; (b) an AUC_{0-24} up to about 200 ng/ml; (c) a T_{max2} of about 3 to about 12 hours.

26. (original) A controlled release pharmaceutical dosage formulation as defined in claim 22 wherein the formulation when administered to humans exhibits (a) a maximum plasma concentration of about 3 to about 20 ng/ml; (b) an AUC_{0-24} of about 30 to about 200 (ng hr)/ml; and (c) a T_{max2} of about 3 to about 12 hours.

27. (canceled).

28. (original) The controlled-release pharmaceutical dosage formulation as defined in Claim 22 wherein the formulation when administered to humans exhibits a plasma peak for the immediate release layer (T_{max1}) between 1 and 5 hours, a plasma peak for the controlled release core (T_{max2}) between 4 and 12 hours, and a plasma trough (T_{min}) between 2 and 7 hours in between the two peak plasma levels.

29. (original) A controlled release pharmaceutical dosage formulation as defined in claim 22 wherein the formulation when administered to humans provides a Tmax from about 3 to about 12 hours.